

July 31, 2000

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 00-10

Subject: Courtesy Notification of Serial Release Actions

To: Veterinary Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

This notice is to inform you that effective September 1, 2000, the Center for Veterinary Biologics (CVB), Inspection and Compliance will no longer provide the Veterinary Biologics Action Report (VBAR) facsimile or telephone notification of serial release actions. CVB will still provide telephone notification, to the appropriate firm official, of serials selected for testing.

Inspection and Compliance has historically provided the above notifications as a courtesy to the veterinary biologics industry. During a recent re-evaluation of our critical processes, we found that a large portion of CVB's limited resources were being used to support this time-consuming process. Further review indicated that this service does not appear to enhance the CVB's mission as it relates to the Virus-Serum-Toxin Act of 1913.

As always, the signed APHIS Form 2008 will be the official firm notification of product release and will be returned to firms by the United States Postal Service. In an effort to expedite notification, we will make provisions to return processed APHIS Form 2008's by courier mail (using a completed **prepaid** air bill) upon request. We will retain these air bills in a secured area and notify you when the supply is running low.

APHIS should determine final disposition 14 days after receipt of samples (3 days for diagnostics) **or** 24 hours following the receipt of the APHIS Form 2008 if the sample selection period has already passed. The returned APHIS Form 2020 documents the assigned sample code number, signature and date received at the laboratory in Ames, Iowa. **Please consider submission and mail delivery before requesting a serial status from our office.**

We realize this procedural change will cause an additional delay in product marketing for some firms and apologize for the inconvenience. However, this measure is necessary to allow continued operation of the core activities that directly support our mission. We will continue to work towards electronic submission and notification as it pertains to our ongoing information management project.

Steven A. Karli
Director
Inspection and Compliance